K131162

2. 510(k) Summary

General Information

Classification:	Class II (special controls)
Classification No.:	21 CFR 878.4400
Common Name:	Electrosurgical cutting and coagulation device and accessories.
Product Code(s):	OUB, NEY
Trade Name:	miraDry System
Submitter:	Miramar Labs, Inc. 445 Indio Way Sunnyvale, CA 94085 USA Tel: 408-940-8700 Fax: 408-940-8795
	FDA Registration No.: 3008082710
Contact:	Kathy O'Shaughnessy, PhD VP, Clinical/Regulatory/Quality
Date prepared:	10/8/2013

OCT 2 5 2013

Intended Use

The miraDry System bears the following Indications for Use statement that is identical to the FDA authorized indications for use for the predicate.

> The miraDry System is indicated for use in the treatment of primary axillary hyperhidrosis.
>
> Note: The miraDry System is not indicated for use in the treatment of hyperhidrosis related to other body areas or generalized hyperhidrosis.

Predicate Device

miraDry System – K103014
Cleared: January 28, 2011

Device Description

The miraDry System is a microwave device designed to heat tissue located at the dermal- hypodermal interface where the axillary sweat glands reside using a surface contact applicator. The miraDry System consists of: the MD4000-MC Console; the MD4000-HP miraDry Handpiece; and a disposable, sterile MD4000-BT miraDry bioTip that snaps onto the Handpiece to provide a sterile protective cover.

As described in K103014, the miraDry System also includes Class I components/accessories. The MD4000-TS template system is a required component for the miraDry treatment as well as the MD4000-PK priming kit. The MD4000-PK priming kit is required when the system is initially set up at a user facility. Optional accessories include an Armrest and disposable ice packs.

The MD4000-MC Console is a software-driven device which contains circuit boards, a microwave generator, integrated vacuum and cooling systems, and an integrated touch-screen user interface.

The non-invasive miraDry Handpiece is specifically designed to deliver microwave energy to the skin at specified frequency and power levels. The proximal end of the Handpiece has a cable bundle and a console connector that supplies the energy and cooling to the Handpiece. The distal end has a sterile, disposable barrier, the miraDry bioTip, which contacts the patient.

The technological characteristics and the principles of operation for the MD4000 miraDry System are the same as the predicate miraDry System.

Materials

All materials used in the manufacture of the modified miraDry System have been demonstrated to meet strict design requirements, including requirements for durability and biocompatibility, and are therefore suitable for use under the anticipated conditions of use associated with the device. There are no changes in materials that raise questions of safety or effectiveness.

Testing

Based on the risk assessment of the modifications, bench testing and pre-clinical testing were performed to ensure continued conformance to all product specifications, and equivalence to the predicate device.

The miraDry System has been shown to conform to the applicable requirements of the following:

- IEC 60601-1:2005 + A1:2012 Medical Electrical Equipment Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2:2007 Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility
- IEC 60601-1-6:2010 Medical electrical equipment Part 1-6: General requirements for safety – Collateral Standard: Usability
- IEC 60601-2-6:2012 Medical electrical equipment Part 2-6: Particular requirements for the safety of microwave therapy equipment.

Summary of Substantial Equivalence

The MD4000 miraDry System is substantially equivalent to the predicate device, the miraDry System cleared under K103014. The indications for use and technological characteristics are equivalent; therefore, the miraDry System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Miramar Labs, Incorporated
Ms. Kathy O'Shaughnessy
Vice President, Clinical/Regulatory/Quality
445 Indio Way
Sunnyvale, California 94085

October 25, 2013

Re: K131162
Trade/Device Name: miraDry System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: OUB, NEY
Dated: October 8, 2013
Received: October 9, 2013

Dear Ms. O'Shaughnessy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. Indications for Use Statement

510(k) Number: (if known) K131162

Device Name: miraDry System

Indications for Use: The miraDry System is indicated for use in the treatment of primary axillary hyperhidrosis.

Note: The miraDry System is not indicated for use in the treatment of hyperhidrosis related to other body areas or generalized hyperhidrosis.

X	AND/OR	
Prescription Use (Per 21 CFR 801 Subpart D)		Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H Chen -A Digitally signed by Long H Chen -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H Chen -A, 0.9.2342.19200300.100.1.1=13003699056 Date: 2013.10.23 09:26:28 -04'00' for MXM

(Division Sign-off)
Division of Surgical Devices
510(k) Number: K131162